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CONFIRMATION NO. APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. 10/049,358 05/17/2002 Maria Davis PB-9944 9975 22840 7590 11/07/2007 **EXAMINER** GE HEALTHCARE BIO-SCIENCES CORP. PATENT DEPARTMENT HUTSON, RICHARD G 800 CENTENNIAL AVENUE ART UNIT PAPER NUMBER PISCATAWAY, NJ 08855 1652 MAIL DATE **DELIVERY MODE** 11/07/2007 **PAPER** 

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)
	10/049,358	DAVIS ET AL.
Office Action Summary	Examiner	Art Unit
	Richard G. Hutson	1652
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply		
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).		
Status		
1) Responsive to communication(s) filed on <u>27 August 2007</u> .		
2a) This action is <b>FINAL</b> . 2b) This	a) ☐ This action is <b>FINAL</b> . 2b) ☐ This action is non-final.	
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is		
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.		
Disposition of Claims		
4)⊠ Claim(s) 15 and 23-26 is/are pending in the application.		
4a) Of the above claim(s) is/are withdrawn from consideration.		
5)⊠ Claim(s) <u>15 and 23-26</u> is/are allowed.		
6) Claim(s) is/are rejected.		
7) Claim(s) is/are objected to.		
8) Claim(s) are subject to restriction and/or election requirement.		
Application Papers		
9) The specification is objected to by the Examine	r	
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.		
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).		
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).		
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.		
Priority under 35 U.S.C. § 119		
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:		
1. Certified copies of the priority documents have been received.		
2. Certified copies of the priority documents have been received in Application No		
3. Copies of the certified copies of the priority documents have been received in this National Stage		
application from the International Bureau (PCT Rule 17.2(a)).		
* See the attached detailed Office action for a list of the certified copies not received.		
Attachmont(c)		
Attachment(s)  1) Notice of References Cited (PTO-892)	4) 🔲 Interview Summan	v (PTO-413)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail D	Pate
3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date	5)	Patent Application

## **DETAILED ACTION**

Applicant's previous amendment of applicant's specification and sequence listing, in the paper of 8/27/2007, is acknowledged. Claims 15 and 21-28 are still at issue and are present for examination.

Upon further examination, the below objection to applicants specification is found to be in order.

## Specification

The disclosure is objected to because of the following informalities:

The amendment filed 4/12/2007 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Applicants reference to page 1, lines 2-5, reciting that provisional 60/150,167 is now U.S. Patent No. 6,410,668 is objected to as new matter. Applicants are reminded that provisional applications do not issue as U.S. Patents. Further applicant's reference to U.S. Patent No. 6,967,250 and U.S. Patent No. 6,949,635 and WO98/43991 as being incorporated in their entirety by reference is considered new matter.

Applicant's attention is directed to the M.P.E.P Section 201.06(c):

## Incorporation by Reference

In a continuation or divisional application, the safeguard (petition and fee under former 37 CFR 1.60(b)) concerning the filing of an application lacking all of the pages of the specification or sheets of drawings of the prior application has not been retained in 37 CFR 1.53(b) since the specification and drawings of a

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continuation or divisional application are not limited to a reproduction or a "true copy" of the prior application. As a safeguard, however, an applicant may incorporate by reference the prior application by including, in the continuation or divisional application-as-filed, a statement that such specifically enumerated prior application or applications are "hereby incorporated herein by reference." The statement may appear in the specification or in the application transmittal letter. The incorporation by reference statement can only be relied upon to permit the entering of a portion of the prior application into the continuation or divisional application when the portion of the prior application has been inadvertently omitted from the submitted application papers in the continuation or divisional application. The inclusion of this incorporation by reference of the prior application(s) will permit an applicant to amend the continuation or divisional application to include any subject matter in such prior application(s), without the need for a petition provided the continuation or divisional application is entitled to a filing date notwithstanding the incorporation by reference.

A priority claim under 35 U.S.C. 120 in a continuation or divisional application does not amount to an incorporation by reference of the application(s) to which priority is claimed. For the incorporation by reference to be effective as a proper safeguard against the omission of a portion of a prior application, the incorporation by reference statement must be included in the specification-as-filed, or transmittal letter-as-filed, or in an amendment specifically referred to in an oath or declaration executing the application. Mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112, first paragraph. In re de Seversky, 474 F.2d 671, 177 USPQ 144 (CCPA 1973). See MPEP§608.01(p).

Applicant is required to cancel the new matter in the reply to this Office Action.

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Further applicants newly submitted sequence listing could not be accepted

for the follwing enclosed reasons.

Appropriate correction is required.

Allowable Subject Matter

Claims 15 and 23-26 are allowable over the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G. Hutson whose telephone number is 571-272-0930. The examiner can normally be reached on M-F, 7:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1009.

Richard G Hutson, Ph.D. Primary Examiner Art Unit 1652

rgh 6/20/2007 ------

Sequence Listing could not be accepted.

If you need help call the Patent Electronic Business Center at (866)

217-9197 (toll free).

Reviewer: Anne Corrigan

Timestamp: Fri Sep 07 17:59:51 EDT 2007

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Reviewer Comments:

<210> 6

<211> 328

<212> DNA

<213> M13mp18

The above <213> response is invalid, per Sequence Rules. The only valid responses are: the Genus species of the organism, "Artificial Sequence," or "Unknown." For "Artificial Sequence" or "Unknown," please explain in the <220>-<223> section. Please give information on the source of the genetic material (e.g., M13mp18 vector). This error appears in Sequences 7 and 10-16.

<210> 8

<211> 189

<212> DNA

<213> Unknown

<220>

<223> Unknown Origin

Please try to give more information in the <223> response regarding the source of the genetic material. Same in Sequence 9.

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